

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*Complete if Known*

Application Number	10/555,011
Filing Date	October 31, 2005
First Named Inventor	Nava ZISAPEL
Group Art Unit	1617
Examiner Name	Jennifer M. Kim
Confirmation No.	9212
Attorney Docket Number	2007-122

Sheet

1

of

5

Attorney Docket Number

2007-122

## U.S. PATENT DOCUMENTS

[illegible]

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code.

<sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kin

of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>a</sup>Applicant is to place a check mark here if English language translation is attached. AB indicates that only an English language abstract is attached.

### INFORMATION DISCLOSURE STATEMENT BY APPLICANT

\*Unique citation designation number. \*See attached Kinds of U.S. Patent Documents. \*Enter Office that issued the document, by the two-letter code. \*For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \*Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. \*Applicant is to place a check mark here if English language translation is attached. AB indicates that only an English language abstract is attached.



# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known

Application Number	10/555,011
Filing Date	October 31, 2005
First Named Inventor	Nava ZISAPPEL
Group Art Unit	1617
Examiner Name	Jennifer M. Kim
Confirmation No.	9212
Attorney Docket Number	2007-122

Sheet

3

of

5

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
/JK/	AC	ARAKI, H.K., et al., "Neuronal Nicotinic Receptor and Psychiatric Disorders: Functional and Behavioral Effects of Nicotine," <i>Jpn. J. Pharmacol.</i> , 2002, pp. 133-138, vol. 88.	
	AD	BENWELL, M.E., et al., "Evidence that tobacco smoking increases the density of (-)(3H)nicotine binding sites in human brain," <i>Journal of Neurochemistry</i> , April, 1988, pp. 1243-1247, vol. 50, no. 4. Medline Abstract No. NLM3346676.	AB
	AE	DOLLINS, Andrew B., et al., "Effect of pharmacological daytime doses of melatonin on human mood and performance," <i>Psychopharmacology</i> , 1993, pp. 490-496, vol. 112.	
	AF	GÄDDNAS, Helena, et al., "Pineal melatonin and brain transmitter monoamines in CBA mice during chronic oral nicotine administration," <i>Brain Research</i> , 2002, pp. 76-83, vol. 957.	
	AG	GARFINKEL, D., et al., "Improvement of sleep quality in elderly people by controlled-released melatonin," <i>The Lancet</i> , August 26, 1995, pp. 541-544, vol. 346.	
	AH	GRAW, Peter, et al., "Early morning melatonin administration impairs psychomotor vigilance," <i>Behavioral Brain Research</i> , 2001, pp. 167-172, vol. 121.	
	AI	HAIMOV, Iris, et al., "Melatonin Replacement Therapy of Elderly Insomniacs," <i>Sleep</i> , 1995, pp. 598-603, vol. 18, no. 7.	
	AJ	HUGHES, Rod J., et al., "The Role of Melatonin and Circadian Phase in Age-related Sleep-maintenance Insomnia: Assessment in a Clinical Trial of Melatonin Replacement," <i>Sleep</i> , 1998, pp. 52-68, vol. 21, no. 1.	
	AK	JAMES, Steven P., et al., "The Effect of Melatonin on Normal Sleep," <i>Neuropsychopharmacology</i> , 1987, pp. 41-44, vol. 1, no. 1.	
	AL	JAMES, Steven P., et al., "Melatonin Administration in Insomnia," <i>Neuropsychopharmacology</i> , 1990, pp. 19-23, vol. 3, no. 1.	
	AM	JORENBY, Douglas, "Clinical Efficacy of Bupropion in the Management of Smoking Cessation," <i>Drugs</i> , 2002, pp. 25-35, vol. 62 Suppl., no. 2.	
/JK/	AN	JORENBY, Douglas, et al., "A Controlled Trial of Sustained-Release Bupropion, A Nicotine Patch, or Both for Smoking Cessation," 2004, pp. 685-691, vol. 340, no. 9.	
Examiner Signature	/Jennifer Kim/		Date Considered 06/02/2009

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.



# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

				Complete if Known	
				Application Number	10/555,011
				Filing Date	October 31, 2005
				First Named Inventor	Nava ZISAPEL
				Group Art Unit	1617
				Examiner Name	Jennifer M. Kim
				Confirmation No.	9212
Sheet	4	of	5	Attorney Docket Number	2007-122

## **NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>	
/JK/	AO	MAQUET, Pierre, "The Role of Sleep in Learning and Memory," <i>Science</i> , November 2, 2001, pp. 1048-1052, vol. 294.		
	AP	MARKUS, Regina P., et al., "Melatonin Nocturnal Surge Modulates Nicotinic Receptors and Nicotine-Induced [ <sup>3</sup> H]-Glutamate Release in Rat Cerebellum Slices," <i>JPET Fast Forward</i> , January 24, 2003, DOI:10.1124/jpet.102.045625, 29 pages		
	AQ	MARKUS, Regina P., et al., "Melatonin Modulation of Presynaptic Nicotinic Acetylcholine Receptors in the Rat Vas Deferens," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 1996, pp. 18-22, vol. 279.		
	AR	PARROTT, A.C., et al., "The Leeds Sleep Evaluation Questionnaire in Psychopharmacological Investigations - A Review," <i>Psychopharmacology</i> , 1980, pp. 173-179, vol. 71, no. 2.		
	AS	PEREIRA, Edna F.R., et al., "Unconventional Ligands and Modulators of Nicotinic Receptors," <i>J. Neurobiol.</i> , 2002, pp. 479-500, vol. 53, no. 4.		
	AT	PICCIOTTO, Marina R., et al., "Nicotinic Receptors in Aging and Dementia," <i>J. Neurobiol.</i> , 2002, pp. 641-55, vol. 53, no. 4.		
	AU	REZVANI, Amir H., et al., "Cognitive Effects of Nicotine," <i>Biol. Psychiatry</i> , 2001, pp. 258-267, vol. 49.		
	AV	RICHARDSON, C. E., et al., "Effect of smoking and transdermal nicotine on colonic nicotinic acetylcholine receptors in ulcerative colitis," <i>Q J Med</i> , 2003, pp. 57-65, vol. 96.		
	AW	RODENBECK, Andrea, et al., "Interactions between evening and nocturnal cortisol secretion and sleep parameters in patients with severe chronic primary insomnia," <i>Neuroscience Letters</i> , 2002, pp. 159-163, vol. 324.		
	AX	SHERER, Michael A., et al., "Effects of Melatonin on Performance Testing in Patients with Seasonal Affective Disorder," <i>Neuroscience Letters</i> , 1985, pp. 277-282, vol. 58.		
/JK/	AY	TARQUINI, Brunetto, et al., "Daytime Circulating Melatonin Levels in Smokers," <i>Tumori</i> , 1994, pp. 229-232, vol. 80.		
Examiner Signature	/Jennifer Kim/		Date Considered	06/02/2009

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.



# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

*Complete if Known*

Application Number	10/555,011
Filing Date	October 31, 2005
First Named Inventor	Nava ZISAPEL
Group Art Unit	1617
Examiner Name	Jennifer M. Kim
Confirmation No.	9212
Attorney Docket Number	2007-122

Sheet

5

of

5

/JK/	AZ	VGONTZAS, Alexandros N., et al., "Chronic Insomnia Is Associated with Nyctohemeral Activation of the Hypothalamic-pituitary-Adrenal Axis: Clinical Implications," <i>J. Clin. Endocrinol. Metab.</i> , 2001, pp. 3787-3794, vol. 86, no. 8.	
/JK/	BA	WETTER, David W., et al., "Tobacco Withdrawal and Nicotine Replacement Influence Objective Measures of Sleep," <i>Journal of Consulting and Clinical Psychology</i> , 1995, pp. 658-667, vol. 63, no. 4.	
/JK/	BB	WOODRUFF-PAK, Diana S., et al., "Nicotinic Cholinergic Modulation: Galantamine as a Prototype," <i>CNS Drug Reviews</i> , 2002, pp. 405-426, vol. 8, no. 4.	
/JK/	BC	ZHDANOVA, Irina V., et al., "Melatonin treatment attenuates symptoms of acute nicotine withdrawal in humans," <i>Pharmacology, Biochemistry and Behavior</i> , 2000, pp. 131-135, no. 67.	
Examiner Signature	/Jennifer Kim/	Date Considered	06/02/2009

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.